REMARKS

A. Examiner Interview

On December 12, 2007, Applicant's representative (Mark Garrett) and Applicant had a telephone conference with Examiner Erezo to discuss all of the pending claims and rejections. Mr. Garrett argued that the Stinson reference's markers were not secured to the intersection of crossed strands, and that, in any event, it made no sense to redesign the stent in the Goicoechea reference to have crossed strands. Examiner Erezo suggested amending the claims to specify how the securing materials secure the intersection. No agreement was reached.

After the call, Applicant discovered that Stinson does indeed teach using its markers to secure the intersection of a crossed strand, such as at lines 39-45 of column 14. Therefore, Applicant's argument about Stinson's markers to Examiner Erezo was incorrect. However, as discussed in more detail below, Applicant maintains that re-designing Goicoechea's stent to provide it with crossed strands is impractical and far from obvious.

B. Claims 1, 2, 25 and 26 Are Patentable over Goicoechea and Stinson

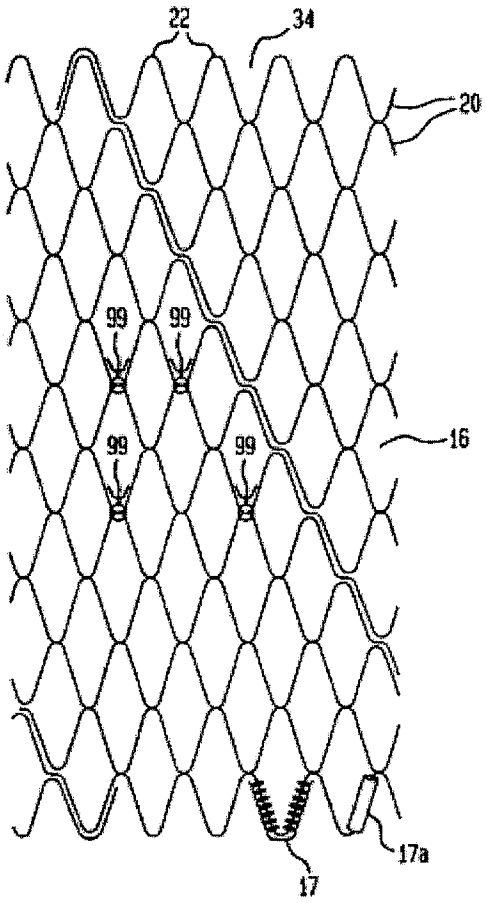
The Office rejects claims 1, 2, 25, and 26 as being obvious over US 5,716,365 to Goicoechea in view of 6,340,367 to Stinson. Applicant respectfully traverses.

Each of these claims involves at least two crossed strands. Claim 1 is directed to a method of securing an intersection formed from two or more crossed strands of a device suitable for implantation into a living being, the intersection defining at least two sections. The method includes "joining the two non-radio opaque securing material segments to secure the intersection formed from the two or more crossed strands of the device suitable for implantation into a living being." Independent claim 25 is directed to a device suitable for implantation into a living being. The device comprises a body having at least two strands crossed to form an intersection, the

intersection defining at least two sections; and a non-radio opaque securing material passed through at least two of the at least two sections, the non-radio opaque securing material being bent at a location and having a non-radio opaque securing material segment on each side of the location, the non-radio opaque securing material segments being joined together using one or more of tying, gluing, heating and compressing. Independent claim 26 is also directed to a device suitable for implantation into a living being. The device comprises a body having at least two strands crossed to form an intersection, the intersection defining at least two sections, each of the at least two strands having a free end separated from the intersection by a strand segment but no other intersection; and a non-radio opaque securing material passed through at least two of the at least two sections, the non-radio opaque securing material being bent at a location and having a non-radio opaque securing material segment on each side of the location, the non-radio opaque securing material segments being joined together.

Goicoechea fails to disclose a stent that involves crossed strands that are secured together. The Goicoechea stent is instead formed by winding distinct parts of the stent (such as proximal part 12, and frustoconical parts 14 and 18) using separate, single wires, each of which is wrapped around a mandrel containing pins located around the mandrel's circumference in a zig-zag pattern and spaced longitudinally along the surface of the mandrel to produce various "hoop" regions that lie in planes perpendicular to the longitudinal axis of the mandrel. These parts are then secured to each other by securing together some or all of the juxtaposed apices 22 of neighboring hoops 20 using securing means 99 such as polypropylene filaments:

FIG. 4A



See col. 8, line 59 – col. 10, line 12.

The Office contends that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Goicoechea to include securing crossing strands instead of just strands having juxtaposed apices ***because tying a securing element between any strands will enhance the security of the tubular structure (stent)***." Action at p. 4 (emphasis added). However, in order to "secure[] crossing strands" in Goicoechea, as the Office proposed, Goicoechea's stent must first be ***re-designed to possess*** crossed strands. As explained below, there is no logical reason why one of ordinary skill in the art would alter Goicoechea so drastically for any reason, much less to "enhance the security of the tubular

structure (stent)," which is not an issue in Goicoechea. The Office is proposing more than the simple substitution of one known element for another:

> The Examiner's contention that "it would have been obvious... to take the apparatus disclosed by Chen and add the encoder taught by Ostermann in order to obtain an apparatus that operates more efficiently by providing lowdelay communications" (Ans. 3) is not sufficient reasoning for combining these references. ***The Examiner has failed to provide sufficient evidence to show that one having ordinary skill in the art would have done what Appellant did*** (*Adams, supra.*). ***This is more than a simple substitution of one known element for another as asserted by the Examiner.*** Accordingly, the Examiner has not set forth a prima facie case of obviousness for claim 21.

See Ex parte Challapali, Appeal No. 2007-2662, Slip Op. at 11 (BPAI Jan. 10, 2008) (emphasis added).

As Jeffery J. Sheldon—the inventor of this application and someone with significant experience in designing and making stents—explains, introducing crossed strands into the non-woven stent of Goicoechea would require a completely new stent design that departs significantly from Goicoechea's described stent design:

> Suggesting that someone of average skill in the stent industry would look to the Goicoechea patent and re-design the stents it discloses to introduce crossed strands is absurd and would require an entirely new design that could only be accomplished by mandrel modifications; the introduction of additional wires; and a winding process change. That would be a significant departure from the design that is disclosed, which has no crossed strands (only adjacent apices from neighboring hoops).

Rule 132 Declaration of Jeffery J. Sheldon at ¶¶ 2-6. Altering Goicoechea's design as suggested by the Office would improperly change its principle of operation. *See In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (reversing obviousness rejection and holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate."). For this reason, the rejection is overcome.

In addition, the Office's purported motivation makes no sense to Mr. Sheldon:

> As someone with at least average skill in the stent-making industry, I do not understand what the USPTO means by its justification that "tying a securing element between any strands will enhance the security of the tubular structure (stent)." I do not know what "security" within Goicoechea's stent design the USPTO is proposing to enhance, or why the USPTO believes any "security" is lacking with Goicoechea's design.

Rule 132 Declaration of Jeffery J. Sheldon at ¶ 7. To the extent that the term "security" as used by the Office is understood, Mr. Sheldon explains that Goicoechea teaches that security is not an issue because not all juxtaposed apices need to be tied together, and that Stinson's tied markers should be minimized and do not impact the "security" of the endoprostheses disclosed:

> Goicoechea actually explains that it is not necessary to secure all of the juxtaposed apices together, so security (if that is what the Office means by it) is not an issue for Goicoechea. While the Stinson patent discloses tying radiopaque markers to crossed strands (col. 14, lines 39-45), the markers are there (according to Stinson) "to improve the radiopacity and the locatability of the endoprostheses in various medical procedures." Col. 2, lines 2-10. Stinson also advocates using as few as possible to a given endoprosthesis. Col. 14, lines 62-65. Nothing in Stinson suggests the markers improve the "security" (whatever the Office intends that to mean) of the disclosed endoprostheses or suggests that they would improve the "security" of other devices if used on them.

Rule 132 Declaration of Jeffery J. Sheldon at ¶ 8. Consequently, the Office has not provided the type of rational basis for its proposed combination that is required to uphold an obviousness rejection on appeal:

> Where the claimed subject matter involves more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement, a holding of obviousness must be based on "an apparent reason to combine the known elements in the fashion claimed." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41 (2007). That is, "there must be some articulated reasoning with ***some rational underpinning*** to support the legal conclusion of obviousness." *Id.*, 127 S. Ct. at 1741 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

See Ex parte Challapali, Slip Op. at 8 (emphasis added).

For each of these reasons, the Office has failed to establish a *prima facie* case of obviousness of any of claims 1, 2, 25, and 26, and the rejection should be withdrawn.

C. Claims 12 and 14 Are Patentable over Goicoechea and Stinson and the Ashley Book of Knots

The Office rejects claims 12 and 14 as being obvious over Goicoechea in view of Stinson as applied to claim 1, and further in view of The Ashley Book of Knots. Applicant respectfully traverses. The combination of Goicoechea and Stinson as applied to claim 1 fails for the reasons set forth above. The Ashley Book of Knots does not remedy that failure. Accordingly, the rejection is overcome and should be withdrawn.

D. Conclusion

Claims 1, 2, 12, 14, 25 and 26 are in condition for allowance. Should Examiner Erezo have any questions, comments, or suggestions relating to this application, he is invited to contact Applicant's attorney at (512) 536-3031.

Respectfully submitted,

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